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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/645,557	08/22/2003	Jhi-Joung Wang	089048-0299	8699
22428	7590	10/11/2006	EXAMINER	
FOLEY AND LARDNER LLP SUITE 500 3000 K STREET NW WASHINGTON, DC 20007			DESAI, RITA J	
			ART UNIT	PAPER NUMBER
			1625	

DATE MAILED: 10/11/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/645,557

Applicant(s)

WANG, JHI-JOUNG

Examiner

Rita J. Desai

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-14 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-14 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 9/22/03, 8/24/06.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: ____.

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DETAILED ACTION

Claims pending 1-14.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-14 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims recite a generic recitation of "R" from straight or branched saturated or unsaturated aliphatic group optionally substituted by an aryl, and an aryl optionally substituted by alkyl chain, and R1 is a divalent moiety of a saturated or unsaturated aliphatic group which may then be optionally substituted.!

The expression "saturated and unsaturated Aliphatic" brings to mind cases as far back as *In re Cavallito* and *grey*, 134 USPQ 370. Lower aliphatic was held unacceptable in *Cavallito* due to the need to provide adequate representative exemplification in the specification for all manner and degree of unsaturation and cyclization to provide a basis of support in the specification for "aliphatic" and unknown substitution.

It is unclear from the claims what is encompassed.

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Claims employing generic language at the point of novelty, such as applicants', neither provide those elements required to practice the inventions, nor "inform the public" during the life of the patent of the limits of the monopoly asserted. The expression could encompass myriad of compounds and applicants claimed expression represents only an invitation to experiment regarding possible compounds.

In re Kirk, 153 USPQ 48. If you the "public" find that it works, I claim it, is not a proper basis of patentability.

Applicants should, in return for a 20 year monopoly be disclosing to the public that which can be actually demonstrated fact.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

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Claims 1-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Buchwald et al (J.Med. Chem., 199, 42-5160-5168)

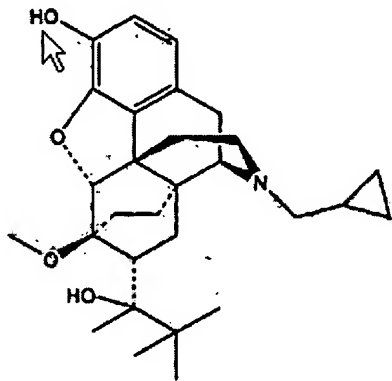
Stinchcomb et al. I Pharmaceutical Research Vol 13 No 10 1996., Vol 12, 1995.

Hu et al US 6225321

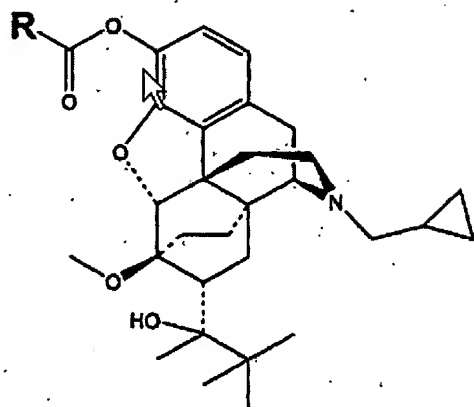
Li-Heng Pao 2000 High Performance liquid chromatographic method for the simultaneous determination of nalbuphine and its prodrug, sebacyl dinalbuphine ester, I dog plasma and application to pharmacokinetic studies in dogs.

Applicants claims are drawn to compositions of buprenorphine mono and dicarboxylic esters for analgesic use.

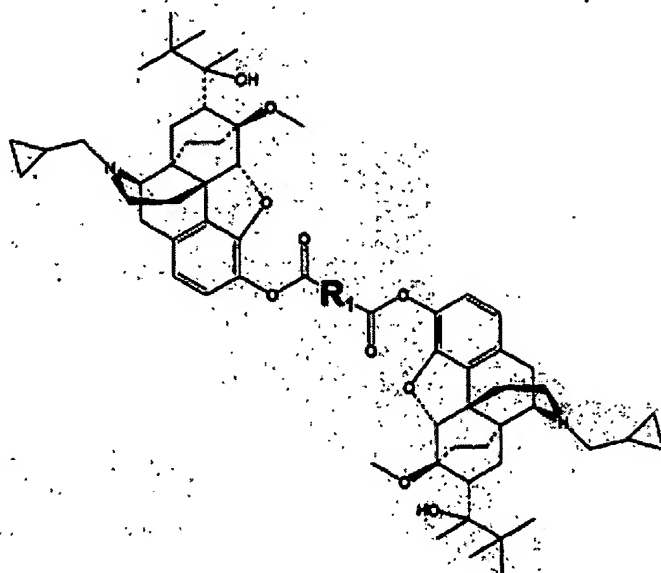
Buprenorphine has the formula



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mono esters and



diesters

Determination of the scope and content of the prior art (MPEP §2141.01)

Stinchcomb et al teaches that **buprenorphine** is a well known analgesic. See page 1519 Introduction.

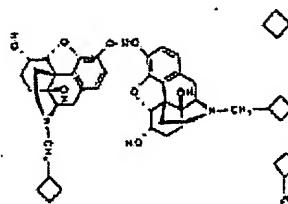
Stinchcomb et al also teaches the prodrug compounds as given on page 1520 with R being a acetyl, ppropyl , butyl, isobutyl. These are the prodrugs. These compounds have been provisoed by the claims.

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Buchwald also teaches the ester prodrugs. See 7a-c. page 5161.

These are the **mono esters of the buprenorphine**.

Hu et al US 6225321, teaches the nalbuphine esters of di , tri and tetra carboxylic acids.



See fig 2. these show the **di esters** of nalbuphine.

ester is disclosed. See table 6 and 7 and column 3 of the reference.

So does Li-Heng pao. See fig 1 on page 242.

Nalbuphine is also an analgesic and acts on the same receptor.

EP 1149 836 Hu Oliver Yoa-pu teaches the polynalbuphine.

US 5750, 534 teaches Nalbuphine , morphine and the buprenorphine.

Ascertainment of the difference between the prior art and the claims (MPEP §2141.02)

The compounds of Stinchcomb et al have been provisoed out, however the R is still any other aliphatic branched or a st. chain.

Hu et al US '321 teaches the nalbuphine di esters and not the buprenorphine.

Finding of prima facie obviousness--rational and motivation (MPEP §2142-2413)

Buchwald et al, Stinchcomb et al teach the same compounds as those of the application. The prior art differs from the compounds claimed herein as alkyl homologs of the claimed compounds. Further applicants compounds proviso out the prior art compounds but include all other alkyl esters. Structurally similar compounds posses similar properties.

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Hu et al '534 teaches the various analgesics Nalbuphine, morphine, buprenorphine. In the '321 patent Hu discloses the di esters of Nalbuphine. Thus teaching the similarity of the analgesics and the possibilities of the diesters of these analgesics. Homology is clearly taught.

Limitation of the claim 6, 12 is also taught in US '321, see column 3 for instance.

While homology is considered to be present, even if true "homology" is not present, such does not defeat the prima facie case of obviousness raised by the art. In *re*Druey et al 50 CCPA 1538, 319 F. 2d 237, 138 USPQ 39 wherein Judge Worley, delivering the Courts's opinion stated:

"We need not decide here whether the compounds in question are properly labeled homologues. It appears to us from the authorities cited by the solicitor and appellants that the term homologue is used by chemists at times in a broad sense, and at other times in a narrow or strict sense. The name used to designate the relationship between the related compound is not necessarily controlling; it is the closeness of that relationship which is indicative of the obviousness or unobviousness of the new compound." 50 CCPA 1541.

Also as the Court stated in *In re Payne et al.*, 606 F. 2d 302, 203 USPQ 245 at 255 (CCPA 1979):

"the name used to designate the relationship between related compounds is not necessarily controlling; it is the closeness of that relationship which is indicative of the obviousness or unobviousness of the new composition."

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In addition , any question of why would one conceive and use the similar compounds (i.e. motivation') is answered by the Court I In re Gyurik et al., 596 F 2d 1012, 201 USPQ 552 at 557.

“ In obviousness rejections based on close similarities in chemical structure, the necessary motivation to make the claimed compound, and thus the prima facie case of obviousness, rises from the expectation that compounds similar in structure will have similar properties.”

The analgesic properties of buprenorphine is known and is not considered to give any patentability weight to the pharmaceutical compositions.

Conclusion

Claims 1-14 are rejected.

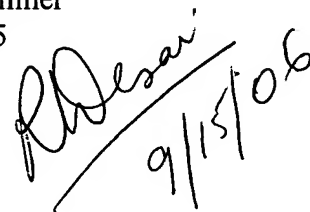
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rita J. Desai whose telephone number is 571-272-0684. The examiner can normally be reached on Monday - Friday, flex time..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thomas McKenzie can be reached on 571-272-0670. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Rita J. Desai
Primary Examiner
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Handwritten signature of Rita J. Desai and the date 9/15/06.

R.D.
September 15, 2006